



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/074,472	05/07/1998	MARK M. RICHTER	09481.0027	2284

22852 7590 06/05/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/074,472

Applicant(s)

RICHTER ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-33 is/are allowed.
- 6) ☒ Claim(s) 34-46 and 50-59 is/are rejected.
- 7) ☒ Claim(s) 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/13/06</u> ; <u>5/11/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2006 has been entered.

Status

2. Claims 30-59 are pending.

Claims 34-46 and 50-59 are rejected.

Claims 30-33 are allowed.

Claims 47-49 are objected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1637

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 34-35, 38-40, 42-46 and 50-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Bohannon (U.S. Patent 5,763,158).

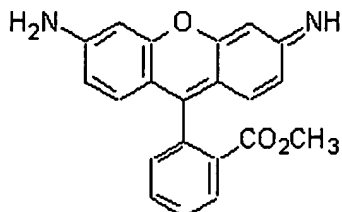
Bohannon teaches a method for detecting an "analyte" in a sample composition (see column 3, lines 18-32) comprising the steps of:

(a) preparing an assay mixture comprising:

(i) said sample composition (see column 4, lines 5-35, where the sample is a "ligand" in the terminology of Bohannon),

(ii) a first reagent comprising an ECL label having a chemical moiety that has electrochemical properties, which ECL label is capable of providing an observed ECL emission (see column 4, lines 10-60 and particularly column 4, line 58 where the ECL label ruthenium (II) tris(bipyridyl) chelate is used),

(iii) a second reagent having an ECL quenching moiety that, when in quenching contact with an ECL label, attenuates the observed ECL emission thereby providing a reduced ECL emission, said ECL quenching moiety comprising at least one benzene moiety (see column 4, lines 25-30 "The mAB is labeled with a quencher molecule capable of reducing detectable reporter activity and see lines 35-46, particularly line 42, where Rhodamine is identified as a quencher whose structure is shown below and comprises a "benzene" moiety)



(b) bringing the assay mixture into contact with a working electrode (see column 4, lines 15-21),

(c) applying a potential to the electrode, thereby enabling an electrochemiluminescence reaction to proceed (see column 4, lines 15-21, “applying a low voltage to an electrode position near the binding site”),

(d) detecting a difference between the observed ECL emission and the reduced ECL emission, thereby confirming the presence of said analyte in the sample solution (see column 4, lines 30-35 and claim 1, step (b)).

With regard to claims 35, 38 and 39, Bohannon teaches benzene carboxylic moieties (see column 4, line 42, where Rhodamine is used and Rhodamine comprises a “benzene carboxylic” moiety).

With regard to claims 40, 42, Bohannon teaches an ECL reagent with ruthenium (II) tris(bipyridyl) chelate (see column 4, line 58).

With regard to claims 43-44, Bohannon teaches attachment of the ECL label and bringing the quencher into quenching contact by interactions of the analyte and binding partner (see column 4, lines 15-35).

With regard to claims 45-46, 50-57, 59, Bohannon teaches the use of antigens and antibodies as ligands (see column 3, lines 17-32).

With regard to claim 58, Bohannon teaches the ligand may be antibodies and the detector can be antibodies (see column 3, lines 17-32).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 36, 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohannon (U.S. Patent 5,763,158) in view of Kuzmin et al (J. Photochem. Photobiol. A: Chem (1995) 87:43-54).

Art Unit: 1637

Bohannon teaches the limitations of claims 34-35, 38-40 and 42 as discussed above. Bohannon teaches the use of any quencher that will quench the ruthenium molecule, expressly claiming "the quencher compound absorbs light at 620 nm" (see claim 26, for example).

Bohannon does not expressly teach the quenchers of quinones, phenols or the use of Osmium as the ECL reagent.

Kuzmin teaches a method for detecting an "analyte" in a sample composition (see page 44, column 2, where SDS micelles and the different micelle concentrations are the analytes) comprising the steps of:

(a) preparing an assay mixture comprising:

(i) said sample composition (see page 44, column 2, where SDS micelles and the different micelle concentrations are the analytes),

(ii) a first reagent comprising an ECL label having a chemical moiety that has electrochemical properties, which ECL label is capable of providing an observed ECL emission (see figure 1 and abstract, where Ruthenium bipyridine is used),

(iii) a second reagent having an ECL quenching moiety that, when in quenching contact with an ECL label, attenuates the observed ECL emission thereby providing a reduced ECL emission, said ECL quenching moiety comprising at least one benzene moiety (see table 1, where several different quinones were used)

(b) detecting a difference between the observed ECL emission and the reduced ECL emission, thereby confirming the presence of said analyte in the sample solution (see figure 3, where SDS micelles resulted in differential quenching).

With regard to claims 35-37, Kuzmin teaches quinone moieties which encompass phenols (see table 1).

With regard to claims 40, 42, Kuzmin teaches an ECL reagent with Ruthenium bipyridine (see abstract, table 1).

Kuzman teaches that Ruthenium and Osmium are known prior art equivalents, but does not exemplify the assay with Osmium (see page 51, column 2, paragraph 4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the phenolic or quinone quenchers of Kuzmin into the method of Bohannon since Bohannon expressly desired quenchers which quench Ruthenium bipyridine and Kusmin teaches compounds which quench Ruthenium bipyridine (see abstract). Further, it would have been prima facie obvious to use osmium for ruthenium since Kuzmin teaches that these are known equivalents. As MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process

for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

Allowable Subject Matter

1. Claims 30-33 are allowed.
2. Claims 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. The following is a statement of reasons for the indication of allowable subject matter: Claims 30-33 and claims 43-59 are drawn to inventions in which the analytes are nucleic acids used in hybridization and for claims 30-33, where the quenching molecule is limited to phenol or benzoquinone and oligonucleotide interactions are required. While Bohannon clearly teaches application of an ECL method with a quencher in a protein based system, Bohannon does not suggest nucleic acid detection methods. The newly cited DiCesare reference suggests nucleic acid detection methods using ECL, but does not suggest the use of a quencher. There is insufficient motivation between the two references to properly combine these references to make a case of prima facie obviousness. In the absence of such motivation, no proper case of prima facie obviousness exists and the claims are novel and unobvious over the prior art.

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


Applicant's amendment and arguments were sufficient to overcome the previously cited art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman
Primary Examiner
Art Unit 1637

5/25/06